K110425

JUL 27 2012

510(k) Summary

5.1 Type of Submission: Traditional

5.2 Submission Date: Dec 28, 2010

5.3 Revised Date: May 21, 2012

5.4 Submitter: Hung Chun Bio-S Co., Ltd.

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Contact person: Ken Liu

Establishment Registration Number: N/A

5.5 Identification of the Device:

Proprietary/Trade Name:	HC-Bios Dental Implant System
Common Name:	Implant, Endosseous, Root-form
Classification Name:	Implant, Endosseous, Root-form
Device Classification:	II
Regulation Number:	872.3640
Panel:	Dental
Product Code:	DZE

5.6 Identification of the Predicate Device:

Predicate Device Name:	Dentium Co., Ltd Implantium
Manufacturer:	Dentium Company Limited
510(k) Number:	K041368

5.7 Intended Use and Indications for Use of the subject device:

The HC-Bios Dental Implant System is a device made of pure titanium metal and titanium alloy intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

5.8 Device Description

The HC-Bios Dental Implant System is a device made of pure titanium metal and titanium alloy intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. It consists of fixture, abutment, mount, mount screw, cover screw, impression coping, analog, impression coping screw and plastic impression cap. Its materials, dimensions, and intended use are similar to devices currently marketed worldwide.

5.9 Non-clinical Testing

A series of in vitro and in vivo preclinical physical, mechanical and biocompatibility tests were performed to assess the safety and effectiveness of the HC-Bios Dental Implant System. The tests were conducted in accordance with ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-12, ISO 11137-1, ISO 14801, ASTM F 543, and ASTM F 1980. All the test results demonstrate the performance of HC-Bios Dental Implant System meets the requirements of its pre-defined acceptance criteria and intended uses.

The results of the non-clinical testing demonstrate that the HC-Bios Dental Implant System is substantially equivalent to the predicate devices.

5.10 Safety and Effectiveness

The result of bench testing indicates that the new device is substantially equivalent to the predicate device.

5.11 Substantial Equivalent Devices

The HC-Bios Dental Implant System submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the Dentium Co., Ltd Implantium which is the subject of K041368. Differences between the devices cited in this section do not raise any new issue of safety or effectiveness.

Item	**Predicate Device** (Dentium Co., Ltd Implantium)	**Proposed Device** (HC-Bios Dental Implant System)
Classification	Class II	Class II
Code or Federal Regulations	872.3640	872.3640
Prescription Medical Devices	Yes	Yes
Intended Use	The device is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, and to restore the patient's chewing function.	The device is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, and to restore the patient's chewing function.
Consisted Instruments	Fixture(implant) Abutment Cover screw Healing abutment Attachment(impression part)	Dental Implants Cover/Healing Screw Abutment Abutment Impression parts Implant impression parts
Material	titanium metal titanium alloy	Grade 4 titanium AISI 316L Stainless Steel
Dimensions of Implants	Four diameters (3.4 to 4.8 mm) Four lengths (8, 10, 12, 14 mm)	Five diameters (3.5 to 7.0 mm) Five lengths (7, 8, 9.5, 11, 14 mm)
Performance Standard	ISO 10993 ISO 14801	ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-12, ISO 11137-1, ISO 14801, ASTM F 543, ASTM F 1980

5.12 Conclusion

After analyzing safety and performance testing data, it can be concluded that HC-Bios Dental Implant System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Hung Chun Bio-S Company, Limited
C/O Mr. Michael Lee
Acmebiotechs Company, Limited
No.45 Minsheng Road
Danshui Town Taipei County
China Taiwan 251

JUL 27 2012

Re: K110425
Trade/Device Name: HC-Bios Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: May 22, 2012
Received: May 22, 2012

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K110425

Indications for Use

510(k) Number (if known):

Device Name: HC-Bios Dental Implant System

Indications for Use:

The HC-Bios Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

This may be accomplished by either a two-stage surgical procedure or a single surgical procedure. If a single surgical procedure is used, single or multiple implants may be inserted (type I, II or III bone) provided good initial stability (> 40 Ncm) is achieved. Not intended for immediate loading.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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